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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,066	09/24/2004	Ulrich Abel	12874-00001-US	1371

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EXAMINER	
DESAI, RITA J	

ART UNIT	PAPER NUMBER
1625	

MAIL DATE	DELIVERY MODE
09/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/509,066	ABEL ET AL.	
	Examiner	Art Unit	
	Rita J. Desai	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9,15 and 16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7, 9, 15 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-7,9, 15 and 16 are pending.

The rejection of claims 1-10, 15 and 16 (now 1-7, 9, 15 and 16)under 35 USC 112 first paragraph still stands.

Applicants explain that the previous response indicated the paragraphs in the publication and are now referring in to pages 13, 11 and 14 of the current specifications. Application point out to page 11 lines 18-22, page 13 lines 1-6.

Page 11 states .The term "heterocycloalkyl" by itself or as part of another substituent includes cycloalkyl groups, wherein up to two CH2 groups may be substituted by oxygen, sulfur or nitrogen atoms, and one or two other CH2 groups may be substituted by one or two carbonyl function(s), carbothionyl function(s), or a carbonyl function and a carbothionyl function, for example pyrrolidine, piperidine, morpholine or

Page 13 lines 1-6 recites

The compounds of Formula 1 may be present as such, or, if they contain acidic or basic groups, in the form of their salts with physiologically tolerable bases or acids. Examples for such acids are: hydrochloric acid, citric acid, trifluoracetic acid, tartaric acid, lactic acid, phosphoric acid, methane sulfonic acid, acetic acid, formic acid, maleic acid, fumaric acid, succinic acid, hydroxysuccinic acid, sulfuric acid, glutaric acid, aspartic acid, pyruvic acid, benzoic acid, glucuronic acid, oxalic acid, ascorbic acid, and acetylglycine. Examples for

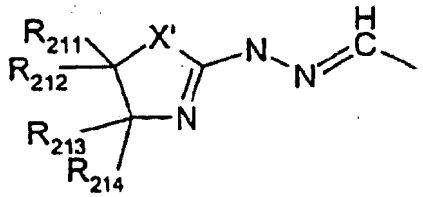
The definition of heteroaryl is given as any R5 and R8, R21 and R22, R24 and R25, and R31 and R32 together with the N can form a 4-8 membered hetero ring optionally containing heteroatoms such as N, O and S.

With the description as given in the claims this would mean forming additional rings on a large core which has its own configuration and thus would produce more interactions between its bonds , spatial arrangements and properties.

Applicants R values are so broad as given below and runs into pages.

R1 means H, C_1-C_6 alkyl, cycloalkyl, or C_1-C_4 alkylcycloalkyl,

R2 means H, C_1-C_{14} alkyl, C_2-C_{14} alkenyl, aryl, C_1-C_4 alkylaryl, heteroaryl, C_1-C_4 alkylheteroaryl, C_2-C_4 alkenylheteroaryl, cycloalkyl, C_1-C_4 alkylcycloalkyl, heterocycloalkyl, C_1-C_4 alkylheterocycloalkyl, $C_mH_{2m+o-p}Y_p$ (with m = 1 to 6, for o = 1, p = 1 to 2m+o; for m = 2 to 6, o = -1, p = 1 to 2m+o; for m = 4 to 6, o = -2, p = 1 to 2m+o; Y = independently selected from the group consisting of halogen, OH, OR21, NH_2, NHR21, NR21R22, and SH, SR21), $(CH_2)_rCH_2NHCOR21$, $(CH_2)_rCH_2OCOR21$, $(CH_2)_rCH_2NHCSR21$, $(CH_2)_rCH_2S(O)nR21$, with n = 0, 1, 2, $(CH_2)_rCH_2SCOR21$, $(CH_2)_rCH_2OSO_2$-R21, $(CH_2)_rCHO$, $(CH_2)_rCH=NOH$, $(CH_2)_rCH(OH)R21$, $-(CH_2)_rCH=NOR21$, $(CH_2)_rCH=NOCOR21$, $(CH_2)_rCH=NOCH_2CONR21R22$, $(CH_2)_rCH=NOCH(CH_3)CONR21R22$, $(CH_2)_rCH=NOC(CH_3)_2CONR21R22$, $(CH_2)_rCH=N$-NHCO-R23, $(CH_2)_rCH=N$-NHC(O)NH-R23, $(CH_2)_rCH=N$-NHC(S)NH-R23, $(CH_2)_rCH=N$-NHC(NH)NH-R23, $(CH_2)_rCH=N$-NHC(NH)-R23, $(CH_2)_rCH=N$-NHCO-CH_2NHCOR21, $(CH_2)_rCH=N$-O-CH_2NHCOR21, $(CH_2)_rCH=N$-NHCS-R23, $(CH_2)_rCH=CR24R25$ (trans or cis), $(CH_2)_rCOOH$, $(CH_2)_rCOOR21$, $(CH_2)_rCONR21R22$, $-(CH_2)_rCH=NR21$, $(CH_2)_rCH=N$-NR21R22,



, and the $(CH_2)_r$-chain elongated group $(CH_2)_rCH=N$-N-(C_3NX'R211R212R213R214) (with X' = NR215, O, S, and R211, R212, R213, R214, R215 being independently H or C_1-C_6 alkyl), $-(CH_2)_rCH=N$-$NHSO_2$ aryl, or $-(CH_2)_rCH=N$-$NHSO_2$ heteroaryl, with r = 0, 1, 2, 3, 4, 5,

R21, R22 are independently H, C_1-C_{14} alkyl, C_1-C_{14} alkanoyl, C_1-C_6 alkylhydroxy, C_1-C_6 alkoxy, C_1-C_6 alkylamino, C_1-C_6 alkylamino-C_1-C_6 alkyl, C_1-C_6 alkylamino-di-C_1-C_6-alkyl, cycloalkyl, C_1-C_4 alkylcycloalkyl, heterocycloalkyl, C_1-C_4 alkylheterocycloalkyl, aryl, aryloyl, C_1-C_4 alkylaryl, heteroaryl, heteroaryloyl, C_1-C_4 alkylheteroaryl, cycloalkanoyl, C_1-C_4 alkanoylcycloalkyl, heterocycloalkanoyl, C_1-C_4 alkanoylheterocycloalkyl, C_1-C_4 alkanoylaryl, C_1-C_4 alkanoylheteroaryl, mono- and di-sugar groups linked through a C atom which would carry an OH group in the sugar, wherein the sugars are independently selected from the group consisting of glucuronic acid and its stereoisomers at all optical atoms, aldopentoses, aldohexoses, including their desoxy compounds (as e.g. glucose, desoxyglucose, ribose,

desoxyribose), or R21 and R22, together with the N, form a ring with 4, 5, 6, 7, or 8 members, which may optionally contain still another heteroatom selected from the group N, O, and S,

R23 independently of R21, has the same meanings as R21, or CH_2-pyridinium salts, CH_2-tri-C_1-C_6 alkylammonium salts, $CONH_2$, $CSNH_2$, CN, or CH_2CN,

R24 independently of R21, has the same meanings as R21, or H, CN, $COCH_3$, COOH, COOR21, CONR21R22, NH_2, or NHCOR21,

R25 independently of R21, has the same meanings as R21, or H, CN, $COCH_3$, COOH, COOR21, CONR21R22, NH_2, or NHCOR21,

R24, R25 together with the N, form a ring with 4, 5, 6, 7, or 8 members, which may optionally contain still another heteroatom selected from the group N, O, and S,

R3 means H, F, Cl, Br, I, OH, OR31, NO_2, NH_2, NHR31, NR31R32, NHCHO, NHCOR31, $NHCOCF_3$, $CH_{3-m}hal_m$ (with hal = Cl, F, and m = 1, 2, 3), or OCOR31,

R31, R32 are independently C_1-C_6 alkyl, or R31 and R32, together with the N, form a ring with 4, 5, 6, 7, or 8 members, which may optionally contain still another heteroatom selected from the group N, O, and S,

R5 means H, C_1-C_{20} alkyl, cycloalkyl, C_2-C_{20} alkenyl, C_2-C_{10} alkinyl, C_1-C_4 alkylcycloalkyl, heterocycloalkyl, C_1-C_4 alkylheterocycloalkyl, aryl, C_1-C_4 alkylaryl, heteroaryl, C_1-C_4 alkylheteroaryl, $C_mH_{2m+o-p}Y_p$ (with m = 1 to 6, for o = 1, p = 1 to 2m+o; for m = 2 to 6, o = -1, p = 1 to 2m+o; for m = 4 to 6, o = -2, p = 1 to 2m+o; Y = independently selected from the group consisting of halogen, OH, OR51, NH_2, NHR51, NR51R52, SH, SR21), $(CH_2)_sCH_2NHCOR51$, $(CH_2)_sCH_2NHCSR51$, $(CH_2)_sCH_2S(O)nR51$, with n = 0, 1, 2, $(CH_2)_sCH_2SCOR51$, $(CH_2)_sCH_2OCOR51$, $(CH_2)_sCH_2OSO_2$-R51, $(CH_2)_sCH(OH)R51$, $(CH_2)_sCOOH$, $(CH_2)_sCOOR51$,

$(CH_2)_sCONR51R52$, with s = 0, 1, 2, 3, 4, 5, mono- and di-sugar groups linked through a C atom which would carry an OH group in the sugar, wherein the sugars are independently selected from the group consisting of glucuronic acid and its stereo isomers at all optical atoms, aldopentoses, aldohexoses, including their desoxy compounds (as e.g. glucose, desoxyglucose, ribose, desoxyribose), with the mono-sugar groups such as aldopentoses, aldohexoses, including their desoxy compounds with R51, R52 which are capable of independently adopting the meaning of R21, R22,

R4, R6, R7 independently mean H, C_1-C_6 alkyl, CO-R41,

R41 independently from R21, has the same meanings as R21,

along with the provisoe

~~complexes~~, wherein the variable groups for Formula Ia may not concomitantly adopt the following meaning~~, except in case of cyclodextrin inclusion complexes~~: R1: H, C_1-C_6 alkyl, R2: C_1-C_6 alkyl, C_2-C_6 alkenyl, R3: H, R4 and R6 identical, and independently H, C_1-C_6 alkyl, CO-R41, with R41 being C_1-C_6 alkyl, aryl, and R7 being H, C_1-C_6 alkyl, Y: O, and for Formula Ib: R1: H, R2: pentyl, 1-pentenyl, 3-pentenyl, 1,3-pentdienyl, R3: H, R4 and R6 being H, and X-R5 being methoxy, Y: O.

thus with only the generic definition given above in pages 11 and pages 13 of the specifications the and only 3 , pyrrolidine, piperidine and morpholine exemplified, applicants have not shown enough commensurate to the scope of the claims.

Applicants have not reduces to practice.

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is

claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of Califomia v. Eli Lilly & Co., 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers,* 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe,* 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.,* 43 USPQ2d 1398.

The MPEP states that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species

to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad genus. *In Gostelli,* the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli,* 872, F.2d at 1012, 10 USPQ2d at 1618.

The Guidelines for Examination of Patent Applications Under 35 USC 112, ¶1, "Written Description" Requirement (Federal Register, Vol. 66, No. 4, pg. 1105, column 3), in accordance with MPEP § 2163, specifically states that for each claim drawn to a genus the written description requirement may be satisfied through sufficient description of a representative number of species by a) actual reduction to practice; b) reduction to drawings or structural chemical formulas; c) disclosure of relevant, identifying characteristics (ie. structure) by functional characteristics coupled with a known or disclosed correlation between function and structure. The analysis of whether the specification complies with the written description requirement calls for the examiner to compare the scope of the claim with the scope of the description to determine whether applicant has demonstrated possession of the claimed invention (Federal Register, Vol. 66, No. 4, p. 1105, 3rd column, 3rd paragraph). Below is such comparison.

Yes a few examples have been given , however it does not commensurate to the fraction of the scope of applicants claims.

In Re Sus and Schaefer 134 USPQ 1962 301-310 (affirmed), where the terms "aryl and substituted aryl" were upheld as in violation of 112 1st paragraph not for breadth but for failing to comply with the written description requirement: "While the term 'aryl and substituted aryl radicals' is a broad term, it is not objectionable for this reason alone if the term is (1) supported by the specification, and (2) if it properly defines the novel subject matter described in the specification. The public purpose on which the patent law rests requires the granting of claims commensurate in scope with the invention disclosed. This requires as much the granting of broad claims on broad inventions as it does granting of more specific claims on more specific inventions. It is neither contemplated by the public purpose of the patent laws nor required by the statute that an inventor be forced to accept claims narrower than his invention in order to secure allowance of his patent. It is, however, consistent with this public purpose embodied in the pertinent statutory requirement that the invention claimed shall be no broader than the invention set.forth in the written description forming a part of the specification .

Thus it seems to us that one killed in this art would not be taught by

written description of the invention in the specification that any 'aryl or substituted aryl radical' would be suitable for the purposes of the invention but rather that only certain aryl radicals and certain specifically substituted aryl radicals would be suitable for such purposes."

Thus the rejection still stands.

The rejection of claims 1-7, 9, 15 and 16 under 35 USC 112 still stands .

The various R2, R3, R5 with the numerous variables and permutations makes the claim nebulous and the art being so unpredictable applicants need to provide more.

There is no data and guidance that these various diseases such as tumors and or parasites administered in an "effective" amount does in fact treat a tumor or parasites. The specification have some IC70 activity for some 29 compounds, that too it ranges from .0030 to .3000 and is no indication that this does treat tumors or parasites.

The rejection of the claims 1-7, 9, 15 and 16 under 35 USC 103 over US 4584377 , US 4673678, US 5166208 still stands.

Applicants R definitions include all the various sugars and other groups and hence these groups would inherently help in making the compounds more soluble.

The rejection still stands.

The double patenting rejections over US 20050215579 and 20050153997 has been withdrawn as applicants have filed a terminal disclaimer.

Conclusion

Claims 1-7, 9, 15 and 16 still stand rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

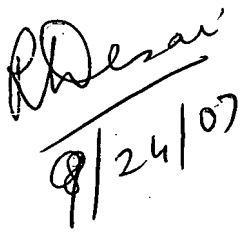
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, flex time..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rita J. Desai
Primary Examiner
Art Unit 1625



R.D.
September 24, 2007